DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 11/11/11, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Allowable Subject Matter

2. Claims 19-20 are allowable. The claimed compounds have been searched and are deemed free of the prior art. Furthermore, it would not have been obvious to selected the closest structurally related compound(s) taught by the prior art for modification since the closest structurally related compound(s) are disclosed as non-specific D2L/D3 dopamine receptor agonists and, furthermore, the prior art teach the desire to find compounds which exhibit selectivity for the D3 receptor. As such, a person of ordinary skill in the art would not have selected a non-specific D2L/D3 dopamine receptor agonist for modification to arrive at the instantly claimed compounds.

3. Since the compounds of claims 19-20 are considered enabled and possess written support, the claims are allowed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 10-11 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by *Swart et al* (J Analyt Toxicol 18:71-77, 1994; of record) as evidenced by *Beane* (Advance Lubrication Techniques – available online at http://contrails.iit.edu; of record).**

6. Instant claim 10 is drawn to a pharmaceutical composition comprising **(S)-2-N-propylamino-5-hydroxytetralin** (claim 11, more specifically, as a pure (S)-enantiomer as recited by claim 14) or a pharmaceutically acceptable salt or prodrug thereof (wherein said prodrug is a compound as defined by claim 10), and at least one pharmaceutically acceptable **carrier or adjuvant** selected from the group consisting of **lubricants**, for example. As summarized, the invention reads on claims 10-11 and 14.

7. As discussed in a previous Actions mailed on 10/16/2008 and 5/12/2011, and reiterated largely as follows, Applicant acknowledges that *Swart et al* (J Analyt Toxicol 18:71-77, 1994) "disclose the (S)-enantiomer of 2-N-propylamino-5-hydroxytetralin" (Applicant's Specification, Page 2, Paragraph 0012). Specifically, *Swart et al* identified the compound as a metabolite of S(-)-2-*N*-propyl-*N*-2-thienylethylamino-5-hydroxytetralin (N-0923) using HPLC with UV detection, combined with atmospheric pressure ionization mass spectrometry (entire document and Page 74, Figure 2, Metabolite 4). More specifically, in being subjected to LC/MS (as evidenced by Page 75, Figure 4), *Swart et al* disclose that the compound was exposed to **nitrogen gas** (Page 74, section entitled 'D. Mass spectrometric analysis').

8. As evidenced by *Beane*, nitrogen gas is a lubricant (Page 384, Second Paragraph, "using nitrogen gas as the lubricant").

9. As such, the solution encompasses a "pharmaceutical composition comprising (S)-2-N-propylamino-5-hydroxytetralin… and at least one pharmaceutically acceptable carrier or adjuvant" selected from the group consisting of lubricants, for example.

10. Accordingly, instant claims 10-11 and 14 are anticipated.

11. Applicant traverses. In particular, Applicant argues that *Swart et al* appears to be using water as the adjuvant or carrier, not nitrogen and what *Swart et al* describes is "not a pharmaceutical formulation comprising 2-N-propylamino-5-hydroxytetralin and nitrogen as the lubricant" (Applicant Arguments, Page 2). The argument is not found persuasive. Clearly the (S)-2-N-propylamino-5-hydroxytetralin spray formed using nitrogen as the nebulizing gas as taught by *Swart et al* entails a pharmaceutical composition comprising (S)-2-N-propylamino-5-hydroxytetralin and nitrogen gas. Since, as evidenced by *Beane*, nitrogen gas is a lubricant (Page 384, Second Paragraph, "using nitrogen gas as the lubricant"), the limitations of the claim are met.

12. Applicant further contends that the reliance on *Beane* "is improper" (Applicant Arguments, Page 2). Applicant presumes that *Beane* is applied to "prove Swart contains an 'enabled disclosure' of using nitrogen gas as a lubricant in a pharmaceutical formulation" (Applicant Arguments, Page 3). However, *Beane* is actually applied to explain the meaning of a term used in the primary reference and/or show that a characteristic not disclosed in the reference is inherent. In particular, to explain that nitrogen gas is a lubricant and/or to show that nitrogen gas has the characteristic of being a lubricant.

13. For the foregoing reasons, Applicant's arguments are not considered persuasive. The rejection of claims is maintained. Furthermore, since Applicant does not specifically traverse the

rejection of claim 13 beyond those arguments discussed above and not found persuasive, claim 13 is maintained rejected as follows:

14. Instant claim 13 is drawn to the composition of claim 10 that is adapted for transdermal, transmucosal or parenteral administration. Applicant is advised that use limitations (i.e., adapted for transdermal, transmucosal or parenteral administration) within product claims do not carry patentable weight unless the recitation of the intended use of the claimed invention results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, absent evidence to the contrary, it is asserted that the prior art composition can be adapated for transdermal, transmucosal or parenteral administration.

15. Accordingly, instant claim 13 is also rejected.

Claim Objections

16. Claim 12 is objected to as depending from a rejected base claim.

Conclusion

No new ground(s) of rejection are presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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